

**Notice of Allowability**

Application No.

09/724,571

Applicant(s)

ANDERSON ET AL.

Examiner

Art Unit

Malgorzata A. Walicka

1652

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment of 03/18/05.
2. ☒ The allowed claim(s) is/are 78,84,85 and 132.
3. ☒ The drawings filed on 11 November 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date <u>03/18/05</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                               | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

Art Unit: 1652

The Amendment to claims filed March 18, 2005 are acknowledged. Claims 1-77, 82, 86-131 and 133-134 were previously canceled; claims 81, 83, and 135 are currently canceled. Claim 78 is amended. Claims 78, 84-85 and 132 are pending; claims 79, 84-85 and the rejoined claim 132 (see bellow) are under examination.

### **DETAILED ACTION**

#### **1. Restriction/election**

Claim 78 is generic and allowable. Applicant is entitled to consideration of claim 132 directed to additional species of beta-secretase substrates, which are not recited by claims 84 and 85. Claim 132 is written in dependent form or otherwise includes all the limitations of the allowed generic claim 78 as provided by 37 CFR 1.141.

#### **2. Objections**

##### **2.1. Specification**

Objection to description of Fig. 5 was issued in error and is withdrawn.

##### **2.2. Claims**

Objection to claim 82 is moot because the claim has been canceled.

#### **3. Rejections**

##### **3.1. 35 USC, section 112, second paragraph**

Rejection of claims 81 and 135 made in the Office Action mailed on Dec. 10, 2004 is moot, because the claims have been cancelled.

##### **3.2. 35 USC, section 112, first paragraph**

###### **3.2.1. Lack of written description**

Art Unit: 1652

Rejection of claims 81, 83 and 135 made in the Office Action mailed on Dec. 10, 2004 is moot because the claims have been cancelled.

Rejection of claims 78, 84-85 is withdrawn, because the amended base claim 78 is not lacking the written description of structure.

### **3.2.2. Scope of enablement**

Rejection of claims 78, 84 and claim 85 made in the Office Action mailed on Dec. 10, 2004 is withdrawn, because claim 78 has been amended.

### **3.3. 35 USC section 102**

Rejection of claims 78 and 84 are rejected under 35 U.S.C. 102(b) as being unpatentable over International Publication Number WO96/40885 (WO85) is withdrawn, because claim 78 has been amended.

### **3.4. 35 USC section 103**

Rejection of claim 85 under 35 U.S.C. 103(a) as being unpatentable over International Publication Number WO96/40885 (WO85), and further in view of International Publication Number WO 98/37226 (WO26) is withdrawn, because claim 78 has been amended.

### **3.5. Nonstatutory Double Patenting**

The nonstatutory double patenting rejection of claim 78 and 84 made in the previous Office Actions is withdrawn, because claim 78 has been amended.

## **4. Examiner's amendment**

- (i) Please replace the first paragraph of the specification with:

Art Unit: 1652

This application is a continuation of U.S. Application No. 09/501,708, filed February 10, 2000, now abandoned, which is a continuation-in-part of U.S. Application No. 09/471,669, filed December 24, 1999. U.S. Application No. 09/501,708, filed February 10, 2000 and now abandoned is an application which claims the benefit under 35 U.S.C. 119(e) of U.S. Application Nos. 60/139,172, filed June 15, 1999, and 60/119,571, filed February 10, 1999. Each of these applications is incorporated herein by reference in its entirety. U.S. Application No. 09/471,669, filed December 24, 1999 is an application which claims the benefit under 35 U.S.C. 119(e) of U.S. Application Nos. 60/139,172, filed June 15, 1999, 60/119,571, filed February 10, 1999, and U.S. Application No. 60/114,408, filed December 31, 1998.

(ii) Please amend claim 132 to read:

132. The method of claim 78, wherein the  $\beta$ -secretase substrate has a sequence selected from the group consisting of SEQ ID NO:72, SEQ ID NO:78, [and,] SEQ ID NO:81, and, SEQ ID NO:97 [, and selecting the test compound as capable of inhibiting A $\beta$  production if said  $\beta$ -secretase polypeptide exhibits less  $\beta$ -secretase activity in the presence of the test compound than in the absence of the test compound].

Authorization for this examiner's amendment was given in a telephone interview with Romi Celli and Joe Liebeschuetz on April 22, 2005.

## 5. Allowance

Claims 78, 84-85 and 132 are allowed. The following is examiner's reasons for allowance. Applicants disclose a method of screening for compounds that inhibit production of A $\beta$  (a protein involved in Alzheimer's disease) in which they use a truncated form of the protein of SEQ ID NO: 2, total of 501 amino acid residues, wherein said protein does not contain a transmembrane domain comprising amino acids residues 455-480 (Fig. 5). The closest prior art is U. S. patent 6,420,534 issued to Guerney et al. with valid priority to U. S. provisional application 60/101,594 filed September 24, 1998, which discloses an enzyme of the sequence identical to SEQ ID NO: 2. Guerney, however, identified the transmembrane domain as amino acid residues 392-417, which is not correct. Thus, Applicants' truncated forms of SEQ ID NO: 2 used in the method of claim 78 are novel and nonobvious.

Art Unit: 1652

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

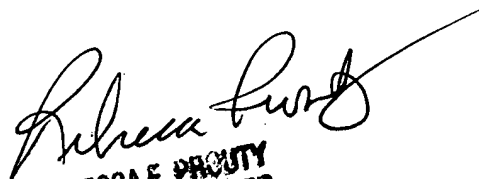
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner

  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
GROUP 1652